January 28, 2021

Acting Administrator Jane Nishida
Environmental Protection Agency
Office of the Administrator, Mail Code 1101A
1200 Pennsylvania Ave., NW
Washington, DC 20460

Submitted via email

Re: Petition for postponement of "Strengthening Transparency" Rule, 86 Fed Reg. 469 (Jan. 6, 2021) pursuant to 5 U.S.C. § 705

Dear Acting Administrator Nishida:

Environmental Defense Fund, Montana Environmental Information Center, Citizens for Clean Energy, American Thoracic Society, Environmental Law & Policy Center, Natural Resources Defense Council, and Union of Concerned Scientists ("Petitioners") write to request that you exercise your authority pursuant to the Administrative Procedure Act, 5 U.S.C. § 705, to postpone the effectiveness of the final rule entitled "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" ("Rule") and published at 86 Fed. Reg. 469 (Jan. 6, 2021), pending judicial review. Because the Rule is set to take effect on February 5, 2021 and a section 705 postponement must be put into place *before* the Rule becomes effective, **we request that you take affirmative action no later than February 4, 2021, to postpone the effectiveness of the Rule**. We further request the opportunity to discuss this petition with the appropriate agency decision-makers as soon as possible.

On January 27, 2021, the U.S. District Court for the District of Montana ruled that the previous Administration's attempt to make the Rule effective immediately upon publication in the Federal Register was unlawful, and the court declared a new effective date of February 5, 2021. *See Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021) ("*EDF v. EPA*") (Attachment A). As explained below, the ruling enables the Environmental Protection Agency ("EPA") to further postpone the effectiveness of the Rule under APA § 705. The court's opinion also "cast[] into significant doubt whether EPA retains any legal basis to promulgate the" Rule at all. *Id.* at 30.

In both purpose and effect, the Rule aims to severely hinder EPA's ability to fulfill its mission to protect human health and the environment. Although the Rule's title makes it sound innocuous, its aims are anything but. The Rule has roots in a more than 25-year-old political and regulatory project of the tobacco and fossil-

fuel industries to fight public health protections by delegitimizing the scientific studies that demonstrate the health and environmental harms their products cause.[1] The scientific community resoundingly opposes the Rule,[2] and EPA's own Science Advisory Board warned that the Rule "risks serious and perverse outcomes."[3]

President Biden has prioritized this Rule for immediate review: in a Day One executive order, he directed that the head of EPA, "as appropriate and consistent with applicable law, shall consider publishing for notice and comment a proposed rule suspending, revising, or rescinding" this Rule "as soon as possible."[4] On January 27, the President issued a memorandum stating: "It is the policy of my Administration to make evidence-based decisions guided by the best available science and data."[5] On the same day, ninety members of the U.S. House of Representatives submitted a letter urging the President "to use all legal and administrative means at your disposal to rollback this harmful rule immediately."[6] A Section 705 postponement is the most legally durable way to accomplish this goal, and will ensure that the Rule never takes effect if the Rule is vacated by the court.

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[1] The effort to restrict studies relying on non-public data "dates back more than 25 years to a strategy developed by tobacco and fossil fuel industry advisers to fight national air quality standards." Marianne Lavelle, *EPA's 'Secret Science' Rule Meets with an Outpouring of Protest on Last Day for Public Comment*, Inside Climate News (May 19, 2020), https://perma.cc/537Y-USJJ . "Industry advisers took an approach of raising doubts about the original scientific studies on the grave health risks" of pollution. *Id.* The strategy—known as "weaponized transparency"—was taken up by chemical companies and other polluting industries as a means of delegitimizing the science behind environmental regulations. Samet & Burke, *Deregulation and the Assault on Science and the Environment*, 41 Ann. Rev. Pub. Health 347, 354–55, 348 (Apr. 2020), https://bit.ly/3b5ginC. After the EPA proposed banning a widely used insecticide linked to brain damage in children, for example, the pesticide company CropLife America petitioned the agency to halt regulatory decisions based on science for which the raw data is not available. *See* Lavelle, *supra*.

[2] *See, e.g.,* Comments of the American Anthropological Association et al. on the Supplemental Notice of Proposed Rulemaking to the Rule "Strengthening Transparency in Regulatory Science," (May 18, 2020) [Docket I.D. EPA-HQ-OA-2018-0259-11498], https://beta.regulations.gov/comment/EPA-HQ-OA-2018-0259-11498. These comments were submitted by thirty-nine of the nation's top scientific, public-health, medical, and academic institutions—including the American Association for the Advancement of Science.

[3] Final Report of EPA's Science Advisory Board at 18 (Apr. 24, 2020), https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf.

[4] "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" § 2(a)(4) (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/.

[5] President Joseph R. Biden, Jr., "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking" (Jan. 27, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.

[6] Letter from Ninety Members of the U.S. House of Representatives to President Joseph R. Biden, Jr. (Jan. 27, 2021) (Attachment B).

Finalized in the waning days of the prior Administration, the Rule is a blatantly politicized attempt to hinder this Administration's ability to rely on the best available science to protect the health of Americans. If it takes effect, it will require this Administration to devalue critical epidemiological and health studies that underpin health protections whenever researchers cannot make the raw data underlying these studies publicly available due to privacy laws, ethics rules, contractual agreements with study participants, or other reasons. Especially in light of the urgent and critical work that EPA must immediately undertake to strengthen public health protections, as directed by President Biden's executive orders, the agency must not allow itself to be hampered by this Rule.

In an attempt to handcuff this Administration to the Rule's new requirements—and prevent you from postponing the Rule before it became effective—the outgoing Administration took the unusual and unlawful step of attempting to make the Rule immediately effective. The district court found that "EPA's decision to make the Final Rule immediately effective on publication was arbitrary, capricious and otherwise not in accordance with law." *EDF v. EPA*, at 31 (quotations omitted). Petitioners now request that this Administration exercise its authority to postpone the effectiveness of the Rule pending judicial review pursuant to 5 U.S.C. § 705.

A postponement of the Rule meets all of the requirements of the Administrative Procedure Act. A postponement is also critical to the agency's ability to fulfill its mandate to protect public health and achieve its stated public health and environmental goals and statutory mandates. The *point* of the Rule is to immediately make it more difficult, if not impossible, for the agency to rely on the best science in developing influential scientific information and promulgating strong public health protections. It creates layers of red tape in the form of requirements the agency must follow in order to consider the results of peer-reviewed published public health research based on human health data that cannot be made public—even when that science provides the best evidence of human health impacts of pollution exposures. And it subjects public health protections to unjustified and unnecessary legal risk. This Administration's ability to quickly and effectively develop strong public health, environmental, and climate protections is severely compromised by this cynical Rule. A postponement is both lawful and warranted.

LEGAL STANDARD

The Administrative Procedure Act explicitly authorizes administrative postponements pending judicial review, providing:

> When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review.

5 U.S.C. § 705 (emphasis added). Section 705 permits an agency to postpone the effectiveness of a regulation on three conditions.

First, in order to "postpone" a regulation, that regulation must not yet have become effective. *Safety-Kleen Corp. v. EPA*, No. 92-1629, 1996 U.S. App. LEXIS 2324, at *2-3 (D.C. Cir. Jan. 19, 1996) (per curiam). In *Safety-Kleen*, the D.C. Circuit held that Section 705 "permits an agency to postpone the effective date of a not yet effective rule, pending judicial review. It does not permit an agency to suspend without notice and comment a promulgated rule." *Id. See also Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (once a regulation is effective it can only be repealed via notice-and-comment rulemaking); *Becerra v. U.S. Dep't of the Interior*, 276 F. Supp. 3d 953, 963-64 (N.D. Cal. 2017); *Merriweather v. Sherwood*, 235 F. Supp. 2d 339, 342 (S.D.N.Y. 2002) ("If a wedding occurs on September 2, one cannot 'postpone' the wedding until September 30 on September 5.").

Second, there must be "pending judicial review." Several courts have concluded that the purpose of the postponement must be related to the judicial review. *See Becerra*, 276 F. Supp. 3d at 964 ("ONRR improperly invoked section 705 to suspend the effective date of the Rule pending its ultimate repeal rather than pending judicial review as required by section 705."); *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 33-34 (D.D.C. 2012) (holding that a postponement under section 705 "plainly must be tied to the underlying pending litigation" and an agency "must have articulated, at a minimum, a rational connection between its stay and the underlying litigation"). *See also* H.R. Rep. No. 79-1980, at 277 (1946) (Section 705 "afford[s] parties an adequate judicial remedy").

Third, the agency must conclude that "justice so requires" the postponement. One court held that, under this prong of the standard, the agency must demonstrate that the postponement meets the four-factor preliminary injunction test. *See Jackson*, 833 F. Supp. 2d at 30. Another court, acknowledging that Section 705 uses different language for the agency's postponement authority and the court's stay authority, found that the "plain language of the statute leaves room to dispute whether such an analysis is required." *California v. Bureau of Land Mgmt.*, 227 F. Supp. 3d 1106, 1123-1124 (N.D. Cal. 2017). That court concluded, however, that the "justice so requires" language must have teeth: "If the words 'justice so requires' are to mean anything, they must satisfy the fundamental understanding of justice: that it requires an impartial look at the balance struck between the two sides of the scale." *Id.* at 1122. Notably, in both cases, the United States argued that meeting the four-factor test was not required. *E.g.*, Defs.' Opp. to Pls.' Mot. for Summ. Judgment at 13-16, *California v. BLM*, No. 3:17-cv-03804, ECF 52 (Aug. 25, 2017). The Department of Justice has pointed out that Section 705 uses different language in its authorization for agency postponements and court stays, establishing two separate standards. *Id.* at 13-14. The Department explained that the practical effects of forcing the agency to apply the preliminary injunction test would be

perverse because an agency would be required to undermine its own litigating position. *Id.* at 15-16. The agency also would need to make a showing that plaintiffs would suffer irreparable harm when information regarding plaintiffs' harm might not be readily available to the agency.

PETITION FOR POSTPONEMENT UNDER 5 U.S.C. § 705

An agency postponement of the Rule under 5 U.S.C. § 705 is authorized because it meets all three requirements of Section 705. It is also warranted, and critical to EPA's ability to fulfill its urgent public health and environmental mission. And, because it is explicitly authorized in the APA, it provides the most certain and legally durable relief from the Rule in the immediate term, while the courts adjudicate the validity of the Rule.

1. The Rule is not yet effective.

First, the Rule is not yet effective, but it is poised to take effect in eight calendar days, on February 5, 2021. In a transparent attempt to block this Administration from relying on Section 705 or other authority to stay the Rule, EPA purported to make it immediately effective contrary to the APA's 30-day window requirement. Plaintiffs brought suit challenging that decision and have now obtained relief on summary judgment. As explained above, the court ruled that the immediate effective date was "arbitrary, capricious and otherwise not in accordance with law." *EDF v. EPA*, at 31. The court also found that "EPA's decision to make the Final Rule immediately effective cut off Plaintiffs' ability to seek postponement under Section 705 as Plaintiffs would have been entitled to do under proper circumstances." *Id.* at 14. The court declared that the "Rule is ineffective until 30 days from its January 6, 2021, date of publication in the Federal Register: February 5, 2021." *Id.* at 31. Given that decision, this is the first possible opportunity for us to make this request—and urgent action is needed on this request before the rule takes effect. Accordingly, we request that you authorize a Section 705 postponement on or before February 4, 2021.

2. A Section 705 postponement would be pending judicial review

Second, the postponement would be pending judicial review, as there are currently at least two lawsuits against the Rule:

- Environmental Defense Fund, Montana Environmental Information Center, and Citizens for Clean Energy challenged the Rule in the District of Montana. *Envtl. Defense Fund v. EPA*, No. 4:21-cv-3 (D. Mont., complaint filed Jan. 11, 2021). The judge granted the motion for partial summary judgment yesterday, but the challenge to the rest of the Rule remains pending.

- A coalition of 18 states and 4 municipalities challenged the Rule in the Southern District of New York. *New York v. EPA*, No. 1:21-cv-00462 (S.D.N.Y, complaint filed Jan. 19, 2021).

Section 705 authorizes administrative relief where judicial review is pending so that parties will not have to comply with a Rule that may not survive review and meets the other requirements for a postponement. As explained below, the Rule is plainly unauthorized and unlawful, and plaintiffs in these cases are likely to prevail in seeking vacatur of the Rule. Indeed, the court described yesterday's ruling as "cast[ing] into significant doubt whether EPA retains any legal basis to promulgate the Final Rule." *EDF v. EPA*, at 30. It makes little sense—indeed, it would be irresponsible—for EPA to be in a position of having to abide by a plainly unlawful rule designed to hinder the agency from fulfilling its protective mandate while that rule is being litigated in the courts.

3. Justice Requires A Postponement

Third, "justice … requires" a postponement. 5 U.S.C. § 705. Whether or not an agency's Section 705 authority is interpreted to require a showing of the four factors for a preliminary injunction, justice warrants a postponement here. In this request, we first explain why a postponement clearly is warranted and required to do justice, and then explain that to the extent the four-factor preliminary injunction test must be met, it is satisfied.

a. A postponement is required so that EPA can fulfill its public health and environmental protection mission.

The purpose and likely effect of the Rule is to make it more difficult for EPA to fulfill its mission of protecting human health and the environment. So that EPA can continue to fulfill that urgent mission while the legality of the Rule is reviewed in the courts, justice requires that EPA postpone the Rule. On one side of the scale is EPA's ability to rely upon the best science to perform its critical mission and improve the lives that depend on strong health and environmental protections. On the other side are requirements—based on entirely unfounded claims of need for "transparency"—that obstruct EPA's ability to assess the health and environmental threats that it is statutorily obligated to address.

For example, EPA is immediately required to begin reviewing the science supporting new particulate matter and ozone standards. The previous Administration finalized decisions not to strengthen the existing standards in December 2020.[7] The President has directed EPA to promptly reconsider those

[7] *See* EPA, Review of the Ozone National Ambient Air Quality Standards, 85 Fed. Reg. 87,256 (Dec. 31, 2020); EPA, Review of the National Ambient Air Quality Standards for Particulate Matter, 85 Fed. Reg. 82,684 (Dec. 18, 2020).

decisions—which will require assessing the best science about the harm caused by the pollutants at issue.[8] Even if EPA determines not to undertake a reconsideration, but instead to move forward on the next round of 5-year reviews of those standards, *see* 42 U.S.C. § 7409(d)(1), it must immediately begin reviewing the public health science showing harms from exposures to various ambient levels of the pollutants. That science, based on actual human health data from persons exposed to pollution, is exactly the type of "dose-response" science that is the target of the Rule.

Reliance on the best-available scientific evidence has long been "central in the network of laws addressing environmental pollution in the United States." Samet & Burke, *supra* n.1, at 348. "This evidence-grounded starting point has been critical in addressing the myriad sources of environmental pollution … [and] reducing the burden of disease attributable to environmental factors." *Id.* In particular, EPA relies heavily on published, peer-reviewed epidemiological studies, using human health exposure data, that demonstrate the health effects of pollution, chemicals, and other environmental exposures in developing a host of regulations that protect human health. *See id.* at 352.

The Rule's purpose and likely effect is to limit the use of such studies, deviating from long-standing practice in order to undermine the agency's important public health and environmental protections. As Dr. Thomas Sinks, the former Director of the EPA's Office of the Science Advisor with 35 years of experience as a federal government epidemiologist, wrote in a rare "differing scientific opinion" opposing the rule: The Rule "significantly limit[s] scientific studies the EPA considers in regulatory decision-making" by restricting the agency's discretion to consider research for which the underlying data is not publicly available.[9] Because privacy laws, contractual agreements, and ethics rules protect the privacy and confidentiality of research participants, the rule would potentially limit agency consideration of "[t]housands of epidemiological studies" that are critical in setting standards to protect the public but that "rely on personal information that, if disclosed, would violate laws that protect study participants." *Id.* It would also restrict the use of studies for which data cannot be made available for other reasons—for example, because the research was conducted long ago.

While the scope of the Rule is exceedingly broad and it is difficult to predict all of the ways that it could undermine public health and environmental protections, some of its targets are clear. One target is the seminal Harvard University Six Cities study and subsequent studies relying on the same cohort that

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[8] *See* Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis," *supra* n.4; White House Briefing Room, Fact Sheet: List of Agency Actions for Review (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/.

[9] Thomas Sinks, *EPA's Scientific Integrity in Question over Science Rule*, The Hill (Nov. 29, 2020), https://thehill.com/opinion/energy-environment/527872-epas-scientific-integrity-in-question-over-science-rule.

document the adverse health effects of particulate matter. These studies undergird many of the agency's protective air quality regulations. Industries responsible for emissions of particulate matter have long sought to challenge this seminal work, even though its results have been reanalyzed and confirmed by an independent body jointly funded by the automobile industry and EPA. Despite this, the Rule could limit "consideration of [this] pivotal study of the health impacts of air pollution because its data remain unavailable to the public, despite the fact the data have been reanalyzed and confirmed." *Id.* Indeed, a document obtained through the Freedom of Information Act suggests the Six Cities study was a principal target of the rulemaking—a "key example" of the supposed "data transparency" problem.[10]

The Rule's proposal and supplemental proposal were met with overwhelming opposition by scientists both inside and outside the agency. EPA's own Science Advisory Board warned that the Rule "risks serious and perverse outcomes."[11] "[T]here are legitimate legal, ethical, professional and financial reasons," it wrote, "why researchers may be unable or unwilling to fully share 'data'—including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data." *Id.* at 17. The Board noted that EPA and scientific institutions have "recognized that such constraints on availability of data do not prevent studies from being verified in other ways—or preclude those studies from being considered in regulatory decisions." *Id.* It concluded that the agency had provided "minimal justification … for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate," or for how the rule would "improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner." *Id.*

Dr. Sinks predicted the Rule will "create chaos."[12] "Human subjects research is the most predictive data for establishing the human health impact from environmental exposures," he wrote, and disregarding or diminishing that research means "setting aside relevant science"—leading ultimately to "poorly developed rules."[13] The result, he concluded, will be to "compromise the scientific integrity of [EPA's] scientists, the validity of [EPA's] rulemaking, and possibly the health of the American People." *Id.*

EPA also received hundreds of thousands of public comments opposing the rule. The nation's leading scientific and medical organizations weighed in, writing that the Rule would "cripple the EPA's ability to create new air and water

[10] Briefing: Data Transparency, Administrator's Office (Jan. 25, 2017) (Attachment C).
[11] SAB Report, *supra* n.3.
[12] Lisa Friedman, *E.P.A.'s Final Deregulatory Rush Runs Into Open Staff Resistance*, N.Y. Times, Nov. 27, 2020.
[13] Thomas Sinks, Differing Scientific Opinion on the Final Strengthening Transparency in Regulatory Science Rule at 3–4 (Attachment D).

protections." Friedman, *supra* n.12. In one comment, thirty-nine of the nation's top scientific, public-health, medical, and academic institutions—including the American Association for the Advancement of Science, the world's largest scientific society—warned that the rule will "diminish the critical role of scientific evidence in decisions that impact the health of Americans" by "de facto rejecting credible practices used by the scientific community and replacing them with … an unscientific standard to assess the validity of science."[14] It would mean, for example, that EPA "will likely be unable to cite important studies on topics relating to the levels of contaminants in water, air and land; epidemiological studies that describe clinical markers of exposure or effect; and many other studies that are fundamental in understanding and protecting human health." *Id.* The Rule, the institutions wrote, is "not about strengthening science, but about undermining the ability of EPA to use the best available science in setting policies and regulations." The result is to "put[] public health and the environment at risk." *Id.*

The final Rule was unveiled by former Administrator Wheeler at the Competitive Enterprise Institute[15] and published on January 6, 2021, just two weeks before Inauguration Day. The final Rule targets scientific research relying on "dose-response data"—that is, "data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect." 86 Fed. Reg. at 492 (40 C.F.R. § 30.2). Such research is often based on data from human subjects, including patients who agree to give researchers highly personal data including where and how they are exposed to various levels of pollution—data from which they could be personally identified. These studies are central to the agency's development of public-health standards, precisely because they are often the best evidence of how people are affected by air pollution. The Rule establishes barriers to using these studies and binds EPA's discretion by requiring it to give less weight to "pivotal science where the underlying dose-response data" are not "available in a manner sufficient for independent validation." *Id.* at 472; *see id.* at 492 (40 C.F.R. § 30.5(c)). Although the Rule contains an exemption provision, it can only be exercised by the Administrator "and requires the Agency to document the rationale for any exemptions granted." *Id.* at 487; *see id.* at 493 (40 C.F.R. § 30.7). At the very least, that exemption process will slow the Agency's consideration of crucial studies and could expose the Agency to increased legal risk for using the best available science.

In addition to devaluing critical studies because researchers cannot make the raw data available, the Rule creates layers of red tape intended to slow the development of protective regulations. EPA must clearly identify all the science upon which its significant regulations and influential scientific information are

[14] Comments of the American Anthropological Association et al., *supra* n.2. at 2-3.
[15] *See* Competitive Enterprise Institute, News Release: EPA Administrator Wheeler Unveils Final Science Transparency Rule During CEI Forum (Jan. 5, 2021), https://cei.org/news_releases/epa-administrator-wheeler-unveils-final-science-transparency-rule-during-cei-forum/.

based and make that science publicly available. 40 C.F.R. § 30.4. EPA must then identify which studies contain "convincing and well-substantiated evidence of a relationship between exposure and effect," document particular attributes of those studies, identify "pivotal science," and, if the data cannot be publicly released, consider a host of specific factors related to the weight it should give that science, and describe its consideration of those factors. *Id.* § 30.5. The agency must also "describe critical assumptions and methods used in its dose-response assessment and shall characterize the variability and uncertainty of the assessment," and "clearly explain the scientific basis for critical assumptions used." *Id.* And while exemptions are permitted, there too specific documentation is required. *Id.* § 30.7. To be sure, EPA may do many of these things in the ordinary course when it proposes a regulation. But the Rule's *specific, prescriptive requirements* are meant to trip up and delay the agency, and otherwise make it more difficult to promulgate rules, and create litigation bait for various regulated industry interests.

"Justice … requires" a postponement of the Rule pending litigation. On one side of the scale lies EPA's longstanding practice and continued ability to freely use the best available science to protect human health and the environment. EPA's scientists must be able to determine which studies to rely upon when taking up the immediate task of developing protective regulations without having an unscientific, anti-regulatory thumb on the scale.[16] Moreover, EPA must be able to act quickly to protect Americans' health and the environment without having to surmount the various bureaucratic hurdles put in place by the Rule. On the other side of the scale are requirements—based on entirely unfounded claims of "transparency"—aimed directly at hindering the agency's ability to fulfill its mission. As noted above, the Rule clearly aims to slow the agency down and create opportunities for those who wish to challenge protective regulations through litigation. Nowhere in the record for the Rule did the prior Administration identify any problem in need of solving, or point to any example where the lack of publicly available data created or demonstrated a problem with the study's quality or the validity of an agency rulemaking. As the scientific community and EPA's own Science Advisory Board explained to the agency, any additional "transparency" provided by the Rule would be outweighed by the perverse effects it would have on the agency's ability to use the best available science in regulating to protect human health and the environment.

b. A postponement meets the four-factor test for a preliminary injunction.

To the extent it is required, *see supra* pp. 4-5, an administrative postponement of the Rule under Section 705 would also meet the four-factor test for a preliminary injunction. Those factors are (1) a likelihood of success on the merits;

[16] Of course, EPA always retains discretion to decline to consider individual studies or evidence if that decision is reasonable and reasonably explained.

(2) a likelihood that plaintiffs would suffer irreparable harm in the absence of injunctive relief; (3) that the balance of equities favors an injunction; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The final two factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

i. Plaintiffs are likely to succeed on the merits of their challenge.

Plaintiffs have filed challenges to the Rule in the courts. *Supra* pp.5-6. These challenges are likely to succeed because the Rule exceeds EPA's authority. 5 U.S.C. § 706(2)(A). Indeed, as noted above, the recent court ruling concluding that EPA unlawfully set an immediate effective date expressly cast doubt on the underlying legality of the entire Rule. Specifically, the court found that the Rule was subject to the 30-day notice window prior to becoming effective because the Rule is substantive rather than procedural. *EDF v. EPA*, at 22-27. Significantly, as authority for the Rule, EPA relied exclusively on the Federal Housekeeping Statute, 86 Fed. Reg. at 471, which—at most—authorizes EPA to issue *procedural* rules. EPA's opposition to plaintiffs' motion for partial summary judgment acknowledged the inexorable implication: "[I]f the Court . . . concludes that the Final Rule is a substantive rule, then the rule would lack a legal basis because EPA promulgated the rule pursuant to its housekeeping authority, which only permits the promulgation of procedural rules." Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgment at 31 n. 4, *EDF v. EPA* (Jan. 19, 2021). By EPA's own admission, then, the Rule is unauthorized and cannot stand.

The Federal Housekeeping Statute provides:

> The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.

5 U.S.C. § 301.

The Housekeeping Statute, as its name suggests, is limited to rules that "govern internal … affairs." *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). The statute only authorizes "what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'" *Id.* at 310. Courts have repeatedly checked agency attempts to "twist" the Housekeeping Statute to a range of substantive purposes and found those efforts unlawful, including halting an

agency's effort to limit disclosure and inclusion of information in the scientific process.[17]

A critical question in determining whether a rule is procedural is whether it leaves the agency with discretion to disregard the rule in an individual case. *See id.* at 301–02 (substantive rules are "binding" or "have the force of law"); *Boulez v. Comm'r*, 810 F.2d 209, 215 (D.C. Cir. 1987) (procedural rules "do not have the force and effect of law," and are "directory, not mandatory in nature"). If EPA's Rule "binds … the agency itself with the 'force of law'" by limiting the agency's discretion to consider scientific studies, it is a "substantive" rule. *See CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003). The Montana federal district court found that EPA's Rule does precisely that:

> The Final Rule falls outside the realm of a procedural rule because it fails to provide the agency with procedural direction. It is no mere internal house-keeping measure. The Final Rule instead makes a substantive determination of how the agency should weigh particular scientific information in future rulemakings. The Final Rule determines outcomes rather than process.

EDF v. EPA, at 23 (citations omitted).

The Rule is therefore on all fours with the substantive action challenged in *Croplife*. In *Croplife*, the D.C. Circuit determined that an EPA press release proclaiming that the agency would not consider human studies in considering pesticide applications was a substantive action: "EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply 'will not consider' human studies." 329

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[17] *See City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019) (vacating regulations from the Department of Health and Human Services and explaining that defendants "mistakenly rely on their 'housekeeping authority' to support their authority to promulgate the rule" but "[n]one of the statutes cited by defendants provide HHS with the authority to promulgate substantive rules" including the Housekeeping Act); *United States ex rel. O'Keefe*, 132 F.3d at 1255 ("In recent years, several agencies have unsuccessfully attempted to find statutory authority for substantive regulations in the Housekeeping Statute."); *In re Bankers Trust Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (holding regulation requiring subpoenaed party to refuse production of confidential information was not authorized by the Housekeeping Statute and "exceeded the congressional delegation of authority"), *cert. dismissed*, 517 U.S. 1205 (1996); *Exxon Shipping Co. v. United States Dep't of Interior*, 34 F.3d 774, 776-78 (9th Cir. 1994) (holding that the Housekeeping Act did not authorize regulations allowing agency to withhold deposition testimony of federal employees); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 826-27 (S.D. Ohio 1995) (holding that the Housekeeping Act did not authorize a 1953 Defense Department directive on the use of human volunteers in experimental research); *McElya v. Sterling Med. Inc.*, 129 F.R.D. 510, 514 (W.D. Tenn. 1990) (concluding that the Housekeeping Act did not give the Department of Navy authority to create general discovery privilege for persons under its jurisdiction).

F.3d at 881. So too here, the Rule is binding on the agency, *requiring* the agency to devalue a scientific study it could have previously given full consideration if the study fails to meet the new requirement that underlying data and models be publicly available (or available through restricted access). The only possible exception would be if the Administrator exercises his or her discretion to grant an exemption for a given study—but in the Rule, "EPA took the additional step of limiting EPA Administrator discretion to make such decisions." *EDF v. EPA*, at 25.

Fundamentally, the Rule has none of the marks of internal housekeeping and "easily meets the core requirements for a substantive rule." *Id.* at 24.

The Rule also departed from EPA's past practice. Prior to the Rule, in rejecting a challenge to its air quality standards for soot, EPA flatly rejected the assertion that the agency cannot rely on studies for which the underlying data are not publicly available. "If governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them," EPA explained, "then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment."[18] The D.C. Circuit upheld that conclusion. *See Am. Trucking Associations, Inc. v. E.P.A.*, 283 F.3d 355, 372 (D.C. Cir. 2002). "[R]equiring agencies to obtain and publicize the data underlying all studies on which they rely," the court wrote, would be both "impractical and unnecessary." *Id.*

For the foregoing reasons, EPA lacked authority to enact the Rule and plaintiffs are likely to succeed on the merits of their challenges. *See United States ex rel. O'Keefe*, 132 F.3d 1252, 1255 (8th Cir. 1998).

ii. Plaintiffs will be irreparably harmed by the Rule.

The Rule threatens immediate harm to EDF, its members, and other plaintiffs during the period for judicial review.

First, EDF has many members who are research scientists and who have concrete professional and financial interests in being able to conduct scientific research that will be considered by EPA on an equal footing as a basis for informing significant regulatory actions or influential scientific information. These scientists conduct their research because they hope to inform policies that will appropriately protect the communities and populations they study. Some researchers are actively recruiting new study cohort members now, and that effort is impeded by the Rule's requirements, as the researchers must inform potential study participants of the risk that their data may be made public. The Rule thus harms these scientists'

[18] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38652, 38689 (July 18, 1997).

interests by placing them in a difficult double bind—they can either promise potential cohort members their privacy, knowing that the resulting research findings will be less impactful, or risk not being able to do the research at all for want of subjects. They also risk losing grants, or access to new grants, or approval from their research institutions, if they attempt to conform their research to the Rule to ensure it receives the weight it is due. When finding that plaintiffs had standing to seek relief, the Montana district court determined that "[p]laintiffs adequately have alleged that their member-scientists will face immediate financial expenses to conform their research agendas with the Final Rule." *EDF v. EPA*, at 18.

Consider the grant evaluation process used by the institutes and centers of the National Institutes of Health (NIH), on which many researchers depend. *See* Birnbaum Decl. ¶¶ 6, 9 (Attachment E). As federally funded programs, these institutes treat the ability to "contribute to the regulatory decisionmaking of federal agencies" as an "important factor" in deciding whether to fund a given research proposal, weighed as part of the "significance" of the research. *Id.* ¶¶ 8, 10, 13. Under this metric, if research is "unlikely or unable" to form the basis for informing a range of EPA activities because the underlying data cannot be made available, an application to conduct that research would be "noncompetitive and highly unlikely to receive a grant." *Id.* ¶¶ 12–13.

Diminished access to NIH funding will impose immediate and far-reaching financial consequences on EDF members who are research scientists. Dr. Jeremy Sarnat and Professor Johnnye Lewis, for instance, are currently preparing applications to NIH institutes to fund research involving sensitive dose-response data that cannot be disclosed (either to the public or via restricted access) because of the nature of the data, the communities with whom the researchers are working, or both. *See, e.g.*, Sarnat Decl. ¶¶ 7, 9–11 (Attachment F) (panel study collecting detailed biometric, geographic, and geospatial data); J. Lewis Decl. ¶¶ 21, 23, 25 (Attachment G) (toxicity study examining uranium contamination impacts on Laguna Pueblo and Navajo Nation populations). Both researchers have had success obtaining such funding in the past. *See* Sarnat Decl. ¶ 12; J. Lewis Decl. ¶¶ 3, 20, 26. But because the rule will severely constrain EPA's discretion to rely on the research these grants support, they are now unlikely to be funded—potentially costing Dr. Sarnat and Professor Lewis millions of dollars in research funding and creating an "immediate financial crisis" in their labs. *See* J. Lewis Decl. ¶¶ 23, 25–26 ($10 million at stake); Sarnat Decl. ¶ 13 ($3–5 million in funding less likely to be awarded). These harms are not unique: funding from NIH and its institutes is typically "critical to the continued financial viability of environmental health research centers." Birnbaum Decl. ¶ 9; *see also, e.g.*, Balmes Decl. ¶¶ 15–19 (Attachment H) (difficulty recruiting cohort of undocumented children as a result of the rule would risk nearly a dozen jobs); Karagas Decl. ¶¶ 2, 12–13 (Attachment I) (95 percent of research led in 2020 depended on NIH funding).

But if researchers instead attempt to produce rule-compliant research, they will face a different set of costs. Most significantly, they risk losing the trust of disadvantaged communities with which they work, such as Indigenous people, immigrants, and racial minorities. Because of historical mistreatment, members of these communities can be "very reluctant" to participate in scientific research "out of fear of how [their] information may be used, or misused." J. Lewis Decl. ¶¶ 10–11 (discussing the denial of treatment to participants in the Tuskegee Syphilis Study and research that included unauthorized genetic tests on Havasupai Tribe participants' biological samples); *see also* Balmes Decl. ¶¶ 9–10, 17–18 (discussing concerns of participants who are undocumented immigrants). As a result, EDF member scientists have found that it is "critical" to be able to "assure study participants that their participation and associated data will remain confidential"—and have spent "years of work" with specific communities, like Native American Tribes, to develop their trust. J. Lewis Decl. ¶¶ 11, 13, 15–16; Balmes Decl. ¶¶ 9–10, 18. That trust hinges not just on protecting data, but also on study participants' belief that their involvement will impact decision-making that benefits their communities. *See* J. Lewis Decl. ¶¶ 17–18; Balmes Decl. ¶¶ 12, 18. For EDF member scientists who work in these communities, the very act of seeking consent to disclose study participants' sensitive information risks shattering the delicate trust relationships they have built over time—an immeasurable loss that imperils future scientific work in the affected communities. *See* J. Lewis Decl. ¶¶ 18–19, 28–29; Balmes Decl. ¶ 18.[19]

And even if EDF member scientists can navigate these challenges, they must expend time and resources to rework their research agendas to develop rule-compliant methods. For members whose research methods are flatly incompatible with disclosure to the public or the government that may mean the grueling work of shifting to different methods entirely. *See, e.g.*, Balmes Decl. ¶ 16 (explaining that it is not possible to disclose cohort data without identifying unique human subjects); Sarnat Decl. ¶¶ 6, 15 (noting the need to shift research priorities); Karagas Decl. ¶ 15 (similar). Moreover, for members currently preparing grant applications or developing research cohorts, the rule imposes "the immediate challenge of scrambling to figure out how to rebuild" noncompliant studies to "somehow be able to answer" the key research questions "while accommodating both EPA requirements" and community concerns. J. Lewis Decl. ¶¶ 15, 25; *see also* Sarnat Decl. ¶ 14; Balmes Decl. ¶ 17.

[19] The Rule's allowance for researchers to make data available via "restricted access," *see* 86 Fed. Reg. 492, does not resolve the concern of individuals—or Institutional Review Boards—that data be kept confidential in general, including from the government and its agents. *See* Balmes Decl. ¶ 10 (noting the difficulty of obtaining Institutional Review Board approval when data cannot be kept confidential); J. Lewis Decl. ¶¶ 12–15 (similar).

Second, the Rule irreparably harms Petitioners' own organizational interests in advocacy based on the best available science. Petitioners and their members have a strong interest in having EPA fully consider the best available science as a basis for significant regulatory actions and influential scientific information. For example, EDF's mission is to preserve the natural systems on which all life depends by using science and economics to find practical and lasting solutions to the most serious environmental problems. EDF seeks to ensure that chemicals, pollutants, and other health determinants are regulated rigorously and in a manner that aligns with the best available science. *See* Levitan Decl. ¶¶ 4–5 (Attachment J); Stith Decl. ¶ 7 (Attachment K). To advance these missions, EDF regularly employs the best available science in its advocacy, including before EPA. McPartland Decl. ¶¶ 7–14 (Attachment L); Levitan Decl. ¶¶ 4–5; Stith Decl. ¶¶ 5–7. The Rule, however, makes this process more costly and less effective, requiring EDF to divert resources to evaluate whether studies could form a basis for EPA action or are candidates for an exemption, *see* McPartland Decl. ¶¶ 15–22, and diminishing the usefulness of research conducted by scientists the organizations employ or work with. *See* G. Lewis Decl. ¶¶ 1, 8, 13–19.

Likewise, Montana Environmental Information Center is a member-supported advocacy and public-education organization that works to protect and restore Montana's natural environment, including through assuring that state and federal officials comply with and fully uphold laws designed to protect the State's environment and people from pollution and fossil-fuel development. Citizens for Clean Energy is a nonprofit membership organization of Montana citizens whose objective is to convince decision-makers to adopt clean-energy solutions in order to preserve Montanans' health, lifestyle, and heritage and to protect Montana's land, air, water, and communities from the consequences of fossil-fuel development. These organizations' missions thus also depend upon EPA's consideration of the best available science as a basis for significant regulatory actions and influential scientific information. Liebert Decl. ¶¶ 2–4 (Attachment M).

In addition to the examples above, the other Petitioners likewise aim to protect public health and the environment and have a strong interest in EPA's use of rigorous science. They also suffer harm as a result of this Rule.

The Biden-Harris Administration has promised "to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; [and]to reduce greenhouse gas emissions." Executive Order, *supra* n.4. In furthering that policy, the new Administration has pledged to review dozens of harmful rules promulgated in the last four years and propose new protective regulations. *Id.* § 2. The Petitioners intend to promote the use of best available science in developing those policies, but the Rule threatens to

hinder both their advocacy during the period of judicial review, as well as the strength of EPA's rulemaking. Many of these rulemakings will happen in the next few months to a year, *see id.*, inflicting permanent damage on Petitioners' ability to advocate for their members and their missions in the immediate term.

For the foregoing reasons, the Rule threatens to irreparably harm Petitioners and their members (including member researchers) during the period for judicial review.

iii. The balance of equities and public interest favor a postponement of the Rule.

For many of the previously listed reasons that "justice … requires" a postponement, the other preliminary injunction factors favor a postponement. The Rule embodies a dangerous policy of undervaluing some of the most critical science for protecting human health and the environment. It is transparently aimed at making it more difficult for EPA to fulfill its mission and providing litigation opportunities for those who oppose strong regulations. As explained above, it seriously harms the researchers who conduct this critical science, the organizations that advocate for strong protections, and ultimately the people who will suffer the effects of weak regulation, particularly vulnerable communities. On the other hand, no entity can claim harm from a postponement of the Rule. A postponement only means that EPA will continue to rely upon the best available science regardless of whether the raw personal data underlying it is made publicly available. EPA always retains discretion to decline to consider a study if the agency's decision is reasonable and reasonably explained. No entity demonstrated that EPA's practice prior to the Rule caused any problem in the past, and there is no harm in retaining the status quo pending review.

CONCLUSION

We respectfully request that you exercise your authority under 5 U.S.C. § 705 to postpone the Rule's effective date pending judicial review. Because the Rule will take effect on February 5, 2021, after which time you will no longer have authority to issue such a postponement under Section 705, we request that you issue the postponement by February 4, 2021. We further request the opportunity to discuss this petition with relevant agency decision-makers as soon as possible.

Sincerely,

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